Approval Date: March 28, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-162

B. Sponsor

Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
PO Box 6457
St. Joseph, MO 64506-0457

C. Proprietary Name

Tripelennamine Hydrochloride Injection

D. Established Name

tripelennamine hydrochloride

E. Dosage Form

Injectable solution

F. Amount of Active Ingredient

20 mg/mL

G. How Supplied

250 and 500 mL vial sizes

H. Dispensing Status

Rx

I. Dosage Regimen

2.5 mL per 100 lb of body weight IM in horses and IV or IM in cattle.

J. Route of Administration

IM in horses, IV or IM in cattle.

K. Species/Class

Cattle and horses

L. Indication

For use in cattle and horses in conditions in which antihistaminic therapy may be expected to lead to the alleviation of some signs of disease. Dose may be repeated in 6 to 12 hours if necessary.

M. Reference Listed New Animal Drug

Re-Covr® Injection, NADA 006-417

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Under the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA. The ANADA sponsor relies on the target animal safety and drug effectiveness and human food safety data in the pioneer's new animal drug application. Ordinarily the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. A tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirements of an *in vivo* bioequivalence study for the generic product, Tripelennamine HCl Injection. The generic product is administered as a solution and contains the same active and inactive ingredients in the same concentration as the pioneer product.

III. HUMAN FOOD SAFETY

Tolerance
A tolerance has not been established for tripelennamine HCl.

Withdrawal Time
When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal times for tripelennamine HCl injection in cattle are: four days following the last treatment for the edible tissues and 24 hours (two milkings) after the last treatment for milk. Tripelennamine is not for use in horses intended for food.

Regulatory Method for Residues
An official analytical method for the detection of residues of tripelennamine in tissues and milk has not been designated.

Expiry Time
24 months.

IV. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, And Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Tripelennamine Hydrochloride Injection, when used under its proposed conditions of use, is safe and effective for the labeled indications.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.